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The American Society for Stereotactic and Functional Neurosurgery Position Statement on Laser Interstitial Thermal Therapy for the Treatment of Drug-Resistant Epilepsy

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Magnetic resonance image–guided laser interstitial thermal therapy (MRgLITT) is a novel tool in the neurosurgical armamentarium for the management of drug-resistant epilepsy. Given the recent introduction of this technology, the American Society for Stereotactic and Functional Neurosurgery (ASSFN), which acts as the joint section representing the field of stereotactic and functional neurosurgery on behalf of the Congress of Neurological Surgeons and the American Association of Neurological Surgeons, provides here the expert consensus opinion on evidence-based best practices for the use and implementation of this treatment modality. Indications for treatment are outlined, consisting of failure to respond to, or intolerance of, at least 2 appropriately chosen medications at appropriate doses for disabling, localization-related epilepsy in the setting of well-defined epileptogenic foci, or critical pathways of seizure propagation accessible by MRgLITT. Applications of MRgLITT in mesial temporal lobe epilepsy and hypothalamic hamartoma, along with its contraindications in the treatment of epilepsy, are discussed based on current evidence. To put this position statement in perspective, we detail the evidence and authority on which this ASSFN position statement is based.

KEY WORDS: Laser interstitial thermal therapy, Epilepsy, Mesial temporal lobe epilepsy, Hypothalamic hamartomas

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EXECUTIVE SUMMARY

Purpose of the Statement

1. To provide an evidence-based, best practices summary to guide healthcare providers in the use of magnetic resonance–guided laser interstitial thermal therapy (MRgLITT) in the management of epilepsy
2. To report a consensus opinion of the American Society for Stereotactic and Functional Neurosurgery (ASSFN) regarding the use of MRgLITT for intractable epilepsy

ABBREVIATIONS: ASSFN, American Society for Stereotactic and Functional Neurosurgery; ATL, anterior temporal lobectomy; DRE, drug-resistant epilepsy; EZ, epileptogenic zone; HH, hypothalamic hamartomas; MRgLITT, magnetic resonance–guided laser interstitial thermal therapy; MTLE, mesial temporal lobe epilepsy; SAH, amygdalohippocampectomy; vEEG, video electroencephalography.

Importance of the ASSFN Statement

1. Stereotactic and functional neurosurgeons are domain-specific experts in the specialty literature and the practical use of stereotactic and open procedures for the surgical management of drug-resistant epilepsy (DRE).
2. Stereotactic and functional neurosurgeons are domain-specific experts in the comparative assessment of benefits, risks, and alternatives of surgical procedures for the management of patients with DRE.

Indications for the Use of MRgLITT as a Treatment Option for Patients With DRE Include All of the Following Criteria

1. Failure to respond to, or intolerance of, at least 2 appropriately chosen medications at appropriate doses for disabling and localization-related epilepsy AND
2. Well-defined epileptogenic foci or critical pathways of seizure propagation accessible by MRgLITT.

Contraindication to Use of MRgLITT

1. Inability to identify the epileptogenic focus (or foci) or critical pathways within epileptogenic networks.
2. Inability to undergo magnetic resonance imaging (MRI) because of medical reasons.
3. Medical contraindications to surgery, eg, unstable cardiac or respiratory conditions, anticoagulants that cannot be stopped, and bleeding diatheses.

Recommendations Are Based on

1. Safety and efficacy demonstrated in multiple peer-reviewed large case series demonstrating the safety and efficacy of MRgLITT in reducing seizure frequency in patients with DRE that is nearly comparable with data obtained from case series of open surgical procedures.
2. Published literature demonstrates that MRgLITT is a less invasive option for many types of focal DREs that involves a shorter hospital stay and less surgical and neurological morbidity as compared to open surgical resection for such common epilepsy etiologies as mesial temporal epilepsy, hypothalamic hamartomas, and focal cortical dysplasia/periventricular nodular heterotopia.
3. Some published studies indicate that MRgLITT may better preserve cognitive functions as compared to open epilepsy surgery.
4. When offered a choice between open surgery and MRgLITT, patients increasingly prefer LITT to open surgery, and many will otherwise refuse surgical treatment at all. Moreover, MRgLITT has also become the first-choice procedure of many epilepsy teams for treatment of many focal epilepsies and has essentially completely supplanted open surgery for epilepsy because of hypothalamic hamartomas. These trends make it unlikely that any randomized trials between MRgLITT and open surgery will be performed.

BACKGROUND AND SUPPORTING LITERATURE

Prevalence and Impact of DRE

Epilepsy is the fourth most common neurological disease with approximately 1.2% of the population in the United States suffering from active epilepsy.¹ This is equivalent to approximately 3.4 million people with epilepsy nationwide, consisting of 3 million adults and 470 000 children. Approximately 1 in 26 people will develop epilepsy during their lifetime.² For patients with epilepsy, 25% to 40% will suffer from persistent seizures despite maximal medical management—otherwise known as DRE.^{3,4}

Persistent seizures and associated neurological comorbidities lead to an approximately 3 times higher mortality rate than the general population, with an estimated decreased life expectancy of 10 yr in people whose epilepsy has a known cause.^{5,6} Furthermore, epilepsy has a significant detrimental impact on employment, social relationships, and overall quality of life for both patients and their families.^{7,8}

However, despite the clear benefits of open epilepsy surgery in reducing mortality and morbidity,^{4,6,9} only approximately 4% of eligible patients undergo this surgery in the United States annually. There was a decreasing rate of epilepsy surgery in the United States from 2003 to 2014, despite the publication of “Epilepsy Across the Spectrum” by the Institute of Medicine in 2012,^{6,10} which strongly advocated for epilepsy surgery. Reasons for this underutilization have been attributed to knowledge gaps (inappropriate optimism about seizure reduction), inability of humans to accurately assess risk, barriers to specialists, and fear of surgery.¹¹

Medical and Surgical Management of DRE

The International League Against Epilepsy has defined DRE as the “failure of adequate trials of 2 tolerated, appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom.”¹² As such, by definition, definitive medical treatment for patients with DRE is inadequate.

Surgical options for DRE depend on seizure type and characteristics of onset and propagation. Surgical procedures for DRE may be divided into ablative/resective (destructive) and neuromodulatory (nondestructive) categories. Complete surgical removal of the brain tissue responsible for seizures (epileptogenic zone, EZ) yields the best outcomes and is associated with the highest rates of seizure freedom. Meanwhile, incomplete removal of the EZ or disconnection of this tissue from the rest of the brain is associated with lower rates of seizure freedom or seizure reduction alone. Fortunately, patients with surgically treated DRE have been shown to have normalization of overall mortality even without complete seizure freedom, as long as there is reduction of seizures with impaired awareness.⁵

Because mesial temporal lobe epilepsy (MTLE) remains the most common form of DRE,^{13,14} overall surgical experience is greatest with this group of patients. Anterior temporal lobectomy (ATL) remains the gold-standard treatment with proven efficacy in 2 class I trials^{14,15} and rates of seizure freedom from 60% to 80% with 2 yr of follow-up.¹⁴⁻¹⁷ Several approaches to selective amygdalohippocampectomy (SAH), with relative sparing of the lateral temporal neocortex, have also demonstrated benefit.^{16,17} In patients with extratemporal lobe epilepsy, surgery has been shown to be effective, albeit with lower rates of seizure freedom in the range of 30% to 60% with 2 yr of follow-up.^{9,18} Despite the overall benefits for quality of life, surgery remains underutilized, at least in part because of concerns regarding its invasiveness, procedural morbidity, and neurocognitive side effects.¹⁹⁻²¹

Over the last decade, MRgLITT has provided a minimally invasive alternative to an open craniotomy for the resection of the EZ. Furthermore, MRgLITT allows surgeons to access to deep structures of the brain with minimal collateral damage of the adjacent white matter and overlying functional cortex—promising fewer neurological side effects and less surgical morbidity. Unlike other ablative techniques of radiofrequency ablation or stereotactic radiosurgery, MRgLITT produces immediate, discrete lesions with

real-time monitoring of temperature and damage estimates that allows for quantification of the ablation and minimization of injury to surrounding brain tissue.^{22,23} As more and more clinical experience has been gained with MRgLITT for DRE, it has become the procedure of choice for many types of epilepsy because of its efficacy, favorable side effect profile, short hospital stay, and rapid return to normal activity as compared to open surgery.

Efficacy of MRgLITT in DRE

Selective ablation of amygdalohippocampal complex is the most widely reported application of MRgLITT for DRE. Across several institutional series, MRgLITT has demonstrated seizure freedom rates of 44% to 78% with at least 1 yr of postoperative follow-up.²⁴⁻³¹ In general, patient selection was based on a diagnosis of DRE and clear evidence of mesial temporal lobe onset. Preoperative evaluation typically included semiology, MRI, neuropsychology, and video electroencephalography (vEEG), as is performed in determination of candidacy for open procedures. Mesial temporal sclerosis was a common finding on MRI but was not necessary if other studies such as vEEG or intracranial EEG allowed for concordance.²⁸ In the largest multicenter series to date, MRgLITT performed in 234 patients from 11 centers across the United States led to seizure freedom in 58% of patients at the 1-yr follow-up.³² Furthermore, 19% of patients benefited from significant seizure reduction—totaling 77% of patients with significant clinical benefit. Two recent meta-analyses have since reported overall rates of seizure freedom to be 55%³³ and 58%³⁴ in patients with MTLE. These rates of seizure freedom are mildly lower than those reported with ATL, as is seen with open SAH as well.¹⁶ The outcomes are certainly superior to continued medical management alone.^{35,36} Moreover, the typical length of stay for mesial temporal MRgLITT is 1 night vs 3 to 4 nights for an standard open ATL.^{37,38} Importantly, when offered a choice between open ATL and stereotactic MRgLITT, an increasing proportion of patients is either willing to sacrifice some of the chance of seizure freedom for the other benefits of the minimally invasive procedure or will simply refuse to consider any open surgery at all.

MRgLITT for the treatment of hypothalamic hamartomas (HH) associated with DRE is the next most reported application of this technology. In the largest 2 series consisting of a total of 129 patients, 81% were free of gelastic seizures at the 6-mo follow-up; and 93% were free of gelastic seizures at the 1-yr follow-up.^{39,40} Although fewer patients experienced resolution of nongelastic seizures (68% free of nongelastic seizures),^{39,41} the overall efficacy of MRgLITT remains high for the treatment of HH. Specifically, a recent review reported that 78% of patients experienced favorable outcomes after MRgLITT, which is further strengthened with a relatively low overall complication rate of 8%.⁴² These outcomes are in contrast to open surgical options, in which seizure freedom rates range from 20% to 54%⁴³⁻⁴⁶ and permanent neurological and endocrinological complications occur in up to 30% to 59% of patients.^{42,45-48} Overall, the published results with MRgLITT for HH are superior to those for cohorts treated by stereotactic radiosurgery, craniotomy, or neuroendoscopy.⁴³ At this time, MRgLITT is the clear procedure of choice for treating

hypothalamic hamartomas, having almost completely supplanted open surgery.

Durability of MRgLITT in DRE

Owing to the relatively recent development of MRgLITT for MTLE, long-term outcome data are limited. Cajigas et al⁴⁹ provided the largest single center cohort with Engel scores with at least 2 yr of follow-up. They reported 62% seizure freedom with an average follow-up of 43 mo. Other studies have published seizure freedom rates between 30% and 52% with a 2-yr follow-up.^{31,50,51} Although a meta-analysis has suggested that seizure freedom rates may wane over time—with *predicted* seizure freedom rates of 64%, 47%, and 42% at 12, 24, and 36 mo, respectively—real-world data consisting of larger cohorts with longer follow-up are needed.³³ Long-term data for other DRE indications remain limited. Given that much of the current longer-term data represent patients operated on in the early experience with MRgLITT, it is expected that these outcomes will improve with time, given the learning curve and the now extant literature regarding optimization of MRgLITT lesions.

Safety of MRgLITT

MRgLITT is significantly less invasive than open surgery, resulting in reduced pain and shorter length of stay, with patients routinely discharged on the first postoperative day in many reports. Furthermore, the ability to monitor the ablation in real-time along with the functionality of adding thermal limits allows surgeons to minimize unintended ablation of structures outside the target zone. Serious neurological complications, such as hemiparesis, and wound infections have not been reported with MRgLITT for MTLE, and clinically significant hemorrhage is rare (<0.5%).³²

The most common complication with MRgLITT for MTLE is a visual field deficit, which has been reported to be clinically significant in 5% to 7% of all patients.^{32,52,53} This complication typically manifests as a contralateral superior quadrantanopsia, which results from posterolateral extension of the ablation into the optic radiations. Overall, this morbidity occurs less frequently than when compared with those reported with standard ATL,⁵⁴ given the proximity of the cranial nerves to the mesial hippocampus. A small number of patients have experienced transient third and fourth cranial nerve palsies, leading to double vision, with MRgLITT for MTLE,^{25,26,28} but these also occur with open surgery.⁵⁴

Youngerman et al⁵⁵ nicely summarized neurocognitive side effects the in their recent review of MRgLITT:

Compared with open resection, [MRgLITT for MTLE] may better preserve neurocognitive functions supported by the lateral temporal neocortex and white matter, though there have been no direct comparisons and many series do not report formal [neurocognitive outcomes]...[Specifically, MRgLITT appears to largely preserve] naming and object recognition following language dominant ablations,^{27,29,31,56-59} functions that commonly decline following

ATL or SAH.^{25,60-62} Verbal memory may decline following dominant [hemisphere MRgLITT],^{29,30,57} however, the risk appears to be lower than with open surgery.^{25,26,58,63,64} Kang et al²⁶ parsed out verbal memory changes and found a decline in non-contextual (word list) verbal memory, which is localized to the mesial structures, but preservation of contextual (narrative) verbal memory, which is supported by the temporal neocortex.

Indications for MRgLITT in DRE

Although the most common published indications for MRgLITT have been MTLE and HH, the technique has been successfully demonstrated in case series for the treatment of DRE associated with localizable epilepsies such as focal cortical dysplasias, tuberous sclerosis, periventricular nodular heterotopias, and cavernous malformations, demonstrating the relative comfort of stereotactic and functional neurosurgeons with the use of this technique for deep-seated lesions.⁶⁵⁻⁷⁷ Similarly, there have been several reports of MRgLITT used to perform a corpus callosotomy,⁷⁸⁻⁸² but the overall experience with this indication remains limited.

CONCLUSION

The popularity of MRgLITT as a surgical option for DRE continues to increase. With the benefit of real-time MRI-based thermal monitoring, it serves as a minimally invasive method capable of immediately creating well-demarcated lesions encapsulating EZs located virtually anywhere in the brain while minimally disrupting to overlying cortex and adjacent white matter structures. Furthermore, patients undergoing MRgLITT experience significantly less pain and shorter lengths of stay compared with open surgery. As such, MRgLITT is becoming a first-line option for the surgical treatment of epilepsy—particularly for deep or otherwise difficult-to-access EZs.³⁷ Although this approach has thus far failed to match seizure freedom rates associated with open resection for indications such as MTLE and extensive focal cortical dysplasia, this shortcoming must be carefully considered and balanced with potential risks including neurocognitive side effects and procedural morbidity. In addition, it is important to remember that MRgLITT does not preclude the option of subsequent more extensive ablations or open surgery. Although long-term outcomes must be compared against proven surgical resection techniques, MRgLITT serves as a minimally invasive option that clearly provides greater benefit in patients with DRE than medical management alone.

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Dr Schwab serves as an investigator for the Medtronic SLATE trial. Dr McKhann serves as an investigator and on the Publications Committee for the Medtronic SLATE trial. Dr Neimat serves as a paid consultant for Monteris.

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